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(54) Thin lance and test sensor having the same

(57) A lance (203) is provided for puncturing skin and producing a sample of blood. The lance comprises a spring (212) having a first end (218) and a second end (220) disposed between a needle (206) and a base (204) wherein the first end of spring is coupled to the base and the second end of the spring is coupled to the needle.

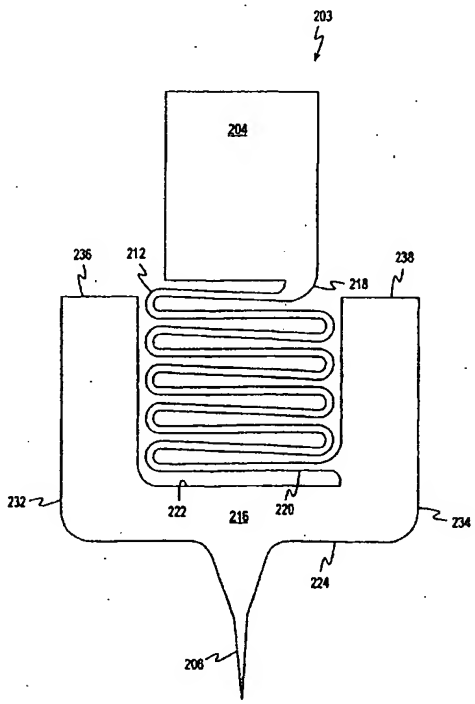

FIG. 4

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Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to blood monitoring devices, and, more particularly, to a thin lance and a test sensor having the same for obtaining a sample of blood.

BACKGROUND OF THE INVENTION

[0002] It is often necessary to quickly obtain a sample of blood and perform an analysis of the blood sample. One example of a need for painlessly obtaining a sample of blood is in connection with a blood glucose monitoring system where a user must frequently use the system to monitor the user's blood glucose level.

[0003] Those who have irregular blood glucose concentration levels are medically required to regularly self-monitor their blood glucose concentration level. An irregular blood glucose level can be brought on by a variety of reasons including illness such as diabetes. The purpose of monitoring the blood glucose concentration level is to determine the blood glucose concentration level and then to take corrective action, based upon whether the level is too high or too low, to bring the level back within a normal range. The failure to take corrective action can have serious implications. When blood glucose levels drop too low - a condition known as hypoglycemia - a person can become nervous, shaky, and confused. That person's judgment may become impaired and that person may eventually pass out. A person can also become very ill if their blood glucose level becomes too high - a condition known as hyperglycemia. Both conditions, hypoglycemia and hyperglycemia, are both potentially life-threatening emergencies.

[0004] One method of monitoring a person's blood glucose level is with a portable, hand-held blood glucose testing device. A prior art blood glucose testing device 100 is illustrated in FIG. 1. The portable nature of these devices 100 enables the users to conveniently test their blood glucose levels wherever the user may be. The glucose testing device contains a test sensor 102 to harvest the blood for analysis. The device 100 contains a switch 104 to activate the device 100 and a display 106 to display the blood glucose analysis results. In order to check the blood glucose level, a drop of blood is obtained from the fingertip using a lancing device. A prior art lancing device 120 is illustrated in FIG. 2. The lancing device 120 contains a needle lance 122 to puncture the skin. Some lancing devices implement a vacuum to facilitate the drawing of blood. Once the requisite amount of blood is produced on the fingertip, the blood is harvested using the test sensor 102. The test sensor 102, which is inserted into a testing unit 100, is brought into contact with the blood drop. The test sensor 102 draws the blood to the inside of the test unit 100 which then determines the concentration of glucose in the blood. Once the results of the test are displayed on the display 106 of the test unit 100, the test sensor 102 is discarded. Each new test requires a new test sensor 102.

[0005] One problem associated with some conventional lancing devices is that the user who regularly self-tests is required to carry at least two instruments - a lance and a test unit. This places a greater burden on the user to remember to carry as well as to maintain two separate devices. Further, a greater amount of space is occupied on the user's person. There can also be an increased expense associated with two separate units.

[0006] Another problem associated with some conventional blood glucose monitoring devices is that the user's blood physically contacts the elements within the testing unit. Cross-contamination can be a problem if the monitoring device is used by more than one user such as in a doctor's office or other clinical setting.

SUMMARY OF THE INVENTION

[0007] A lance is provided for puncturing skin and producing a sample of blood. The lance comprises a spring having a first end and a second end disposed between a needle and a base wherein the first end of integral spring is coupled to the base and the second end of the spring is coupled to the needle.

[0008] The above summary of the present invention is not intended to represent each embodiment, or every aspect, of the present invention. Additional features and benefits of the present invention will become apparent from the detailed description, figures, and claims set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Other objects and advantages of the invention will become apparent upon reading the following detailed description in conjunction with the drawings in which:

FIG. 1 is a top view of a prior art blood glucose testing device;

FIG. 2 is a perspective view of a prior art lance;

FIG. 3 is a perspective view of a test sensor having a thin lance according to one embodiment of the present invention;

FIG. 4 is front view of a thin lance according to one embodiment of the present invention;

FIG. 5 is a perspective view of test sensor according to one embodiment of the present invention;

FIG. 6 is a cross-sectional view of the test sensor illustrated in FIG. 5;

FIG. 7 is an embodiment of a blood glucose monitoring system for use in conjunction with a test sensor having a thin lance according to an alternative embodiment of the present invention;

FIG. 8 is a prospective view of an end cap and a blood glucose monitoring system for use in conjunc-

tion with a test sensor having a thin lance according to a second alternative embodiment of the present invention;

FIG. 9a is a cross-sectional view of the end cap illustrated in FIG. 8; and

FIG. 9b is a cross-sectional view of the end cap illustrated in FIG. 8 with the thin lance extended.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0010] Referring now to FIG. 3, a test sensor having a thin sensor and lance ("sensor/lance") 200 according to one embodiment of the present invention is illustrated. The sensor/lance 200 includes a thin test sensor 202 and a thin lance 203. The thin lance 203 has a base 204 which is coupled to the test sensor 202. The remainder of the thin lance 203 is movable allowing a thin needle 206 to travel downward to puncture a user's skin in order to produce a drop of the user's blood. The test sensor 202 has an inlet 208 through which blood is moved by capillary action into the test sensor 202. The test sensor 202 and the lance 203 are generally thin and flat and each have a thickness of approximately 0.006 inch.

[0011] Referring also to FIG. 4, the thin lance 203 of the sensor/lance 200 will be described in greater detail The illustrated embodiment of the thin lance 203 is formed out of a single piece of metal. A thin spring 212 couples the base 204 to a U-shaped member 216. The spring 212 has a first end 218 and a second end 220, the first end 218 of which is coupled to the base 204 and the second end is coupled to an interior 222 of the U-shaped member 216. The thin needle 206 is formed on an exterior 224 of the U-shaped member. The two sides of the U-shaped member are force receiving members 232,234 for providing movement to the thin needle 206.

[0012] In operation, when a user is testing the glucose concentration of blood, the test sensor 202 remains stationary within a testing device while a force is imparted on to a top portion 236,238 of each force receiving member 232,234. The force receiving members 232,234 are driven downward thus forcing the needle 206 downward into the user's skin. Once the force is removed from the force receiving members 232,234, the spring 212 retracts the needle 206 from the users skin.

[0013] Referring also to FIGS. 5 and 6, the thin test sensor 202 will be described in greater detail. The test sensor 202 comprises a test chamber having a test area 240 disposed between a front panel 242 and a rear panel 244. The test area 240 is designed to allow blood to move from the inlet 208 up the test area 240 via capillary action. An adhesive 246 is disposed on the front panel 242 to adhere the base 204 of the thin lance 203 to the front panel 240.

[0014] A reagent is incorporated into the test sensor 202. The reagent is designed to react with the glucose in the blood which moves up the test area 240. The reaction produces a detectable signal which is indicative of the glucose concentration in the sample of blood. That signal is then measured by a sensor which can measure the concentration of the glucose in the blood based on the signal. The specific reagent incorporated into the test sensor 202 is a function of the type of sensing employed to determine the concentration of glucose in the blood. In the illustrated embodiment of the test sensor 202, electrochemical sensing is employed. The test sensor 202 includes a pair of electrodes 250 (FIG. 6) In electrochemical analysis, the change in current across the electrodes 250 caused by the reaction of the glucose and the reagent is indicative of the concentration of the glucose in the blood. The reaction of the glucose and the reagent creates an oxidation current at the electrodes 250 which is directly proportional to the user's blood glucose concentration. This current can be measured by an appropriate sensor coupled to a pair of terminals 252 corresponding to the electrodes 250 implemented in a glucose monitoring device for use with the sensor/lance 200. The glucose monitoring device can then communicate to the user the blood glucose concentration. An example of an electrochemical testing system is described in detail by commonly-owned U.S. Patent No. 5,723,284 entitled "Control Solution and Method for Testing the Performance of an Electrochemical Device for Determining the Concentration of an Analyte in Blood" which is incorporated herein by reference in its entirety.

[0015] Referring now to FIG. 7, an application of the sensor/lance 200 is in an integrated blood glucose monitoring system 300 which integrates the lancing, the blood harvesting, and a blood glucose analyzer into a single instrument. The integrated blood glucose monitoring system 300 contains a plurality of sensors/lances 200 for use in a plurality of blood glucose self-tests. In operation, a user would activate the system 300 with a switch 304. A new thin sensor/lance 200 is advanced to the test end 302 of the system 300. The user would then press the test end 302 of the system against the user's skin and depress a trigger 306 causing a spring loaded member (not shown) to apply a force to the force receiving members 232,234 of the thin lance 203. The needle 206 would then extend through an opening 308 in the test end 302 of the system 300 to puncture the user's skin. After the needle 206 is fully extended out of the opening 308, the spring 214 would withdraw the needle from the laceration created in the user's skin through the opening 308. Blood emerging from the laceration created in the user's skin is moved from the inlet 208 by capillary action into the test sensor 202. Once the requisite blood sample has been obtained and the requisite time has elapsed for the reaction in the test sensor 202 to take place, the blood glucose monitoring system 300 measurers the signal produced by the reaction and determines the blood glucose concentration of the blood sample. The results of the analysis are communicated to the user via a display 310. The sensor/lance 200 is then ejected from the system 300 and discarded.

[0016] Referring now to FIGS. 8, 9a, and 9b, another application of the sensor/lance 200 is in a disposable, protective end cap 350. In a clinical setting, such as a medical doctor's office where the user is a doctor, nurse, or technician seeing multiple patients, cross contamination is a serious concern. Obviously, components of medical devices which come into contact with one patient's blood can not come into contact with the user or another patient. The end cap 350 protects those who handle the end cap 350 from coming into contact with the needle 206 and any blood disposed thereon after the sensor/lance 200 within the end cap 350 have been used. Only when actuated (during testing), does the needle 206 extend beyond the area bounded by the end cap 350. Accordingly, a user (doctor, nurse, technician) is protected from being punctured with the needle 206 when connecting the end cap 350 to or removing the end cap 350 from the sensor/lance 200.

[0017] A blood glucose monitoring system 360 for use with the disposable end cap 350 having a sensor/lance 200 disposed therein is also illustrated in FIG. 8. The device 360 contains a switch 362 to activate the device 360. A trigger 364 is provided to fire a spring loaded plunger 366 to contact the force receiving members 232,234 which in turn provide movement to the needle 206. The when actuated, the spring loaded plunger 366 rapidly moves downward a predetermined distance to move the force receiving members 232,234 and in turn the needle 206 a predetermined distance causing the needle 206 to extend beyond a test end 352 of the end cap 350 a distance about equal to the needle 206 penetration depth. The distance that the needle 206 extends beyond the test end 352 of the end cap 350 is preferably a distance sufficient to draw a sample of blood for analysis. Once the plunger forces the needle downward, the spring loaded plunger 366 retracts a distance allowing the needle 206 to retract back within the bounds of the disposable end cap 350. Meanwhile, the sample of blood moves though the inlet 208 disposed adjacent to the test end 352 of the end cap 350) of the test sensor 202. Once the requisite blood sample has been obtained and the requisite time has elapsed for the reaction in the test sensor 202, the blood glucose monitoring system 360 measurers the signal produced by the reaction and determines the blood glucose concentration of the blood sample The results of the analysis are communicated to the user via a display 368. The end cap 350 containing the used sensor/lance 200 is then removed from the system 300 and discarded. The end cap 350 and the blood glucose monitoring system 360 have suitable connectors 370, 372 for mating the end cap 350 with the blood glucose monitoring system 360.

[0018] Thus far, only electrochemical analysis to determine the glucose concentration of a blood sample has been discussed in conjunction with the present invention. However, the thin sensor/lance 200 of the present invention can be used with other types of blood glucose testing methods. For example, colorimetric testing may be implemented in the test sensor in conjunction with an alternative embodiment of the present invention. Colorimetric testing is described in commonly-owned U.S. Patent No. 5,723,284 entitled "Control Solution and Method for Testing the Performance of an Electrochemical Device for Determining the Concentration of an Analyte in Blood," which was incorporated herein by reference above.

[0019] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings and will be described in detail herein. It should be understood, however, that it is not intended to limit the invention to the particular forms disclosed, but, to the contrary, the intention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

Claims

1. A lance comprising:

   a base-,
   a spring having a first end and a second end, the first end of the spring coupled to the base-, and
   a needle coupled to the second end of the spring.

2. The lance of claim I further comprising a generally U-shaped body disposed between the second end of the spring and the needle, the U-shaped body having a interior edge and an exterior edge, the second end of the spring being coupled to the interior edge, the needle being coupled to the exterior edge.

3. The lance of claim 2 wherein the base, the spring, the body, and the needle are generally flat.

4. The lance of claim 3 wherein the base, the spring, the body, and the needle are made out of metal.

5. The lance of claim 4 wherein the base, the spring, the body, and the needle are made out of a single piece of metal.

6. A test sensor for use in the determination of the concentration of a chemical in blood, the test sensor comprising:

   a thin test chamber having an inlet, the test chamber being adapted to collect a sample of blood through the inlet; and
   a thin lance coupled to the test chamber, the lance being adapted to puncture skin.

7. The test sensor of claim 9 wherein the thin lance includes:

a spring having a first end and a second end, the first end coupled to the test sensor; and
a needle coupled to the second end of the spring.

8. The test sensor of claim 9 wherein the thin lance includes:

a base;
a thin spring having a first end and a second end, the first end coupled to the base;
a thin, generally U-shaped body having an interior edge and an exterior edge, the second end of the thin spring coupled to the interior edge; and
a thin needle coupled to the exterior edge.

9. The test sensor of claim 9 wherein the test chamber includes a reagent, the reagent being adapted to produce an electrochemical reaction, the test strip further comprising a pair of electrodes coupled to the test area.

10. A test sensor for use in the determination of the concentration of an a chemical in blood, the test sensor comprising:

a housing having a test end with an aperture disposed therein;
a test chamber disposed within the housing, the test chamber having an inlet disposed adjacent to the aperture in the test end, the test chamber being adapted to collect blood through the inlet; and
a lance disposed within the housing and coupled to the test sensor, the lance being adapted to extend through the aperture in the test end.

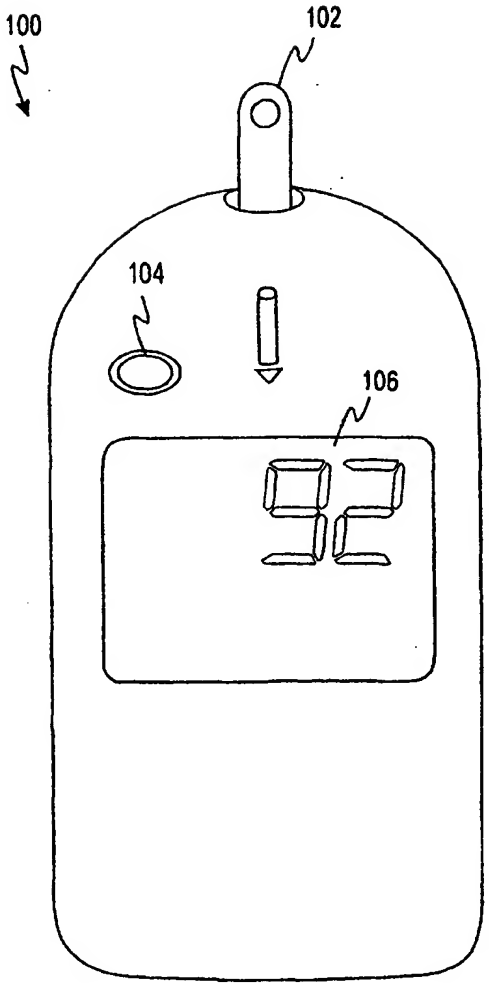

FIG. 1
(Prior Art)

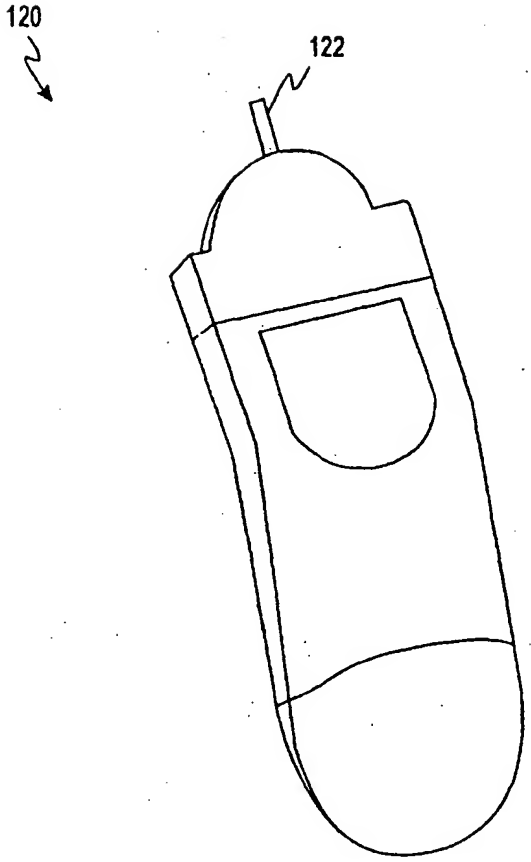

FIG. 2
(Prior Art)

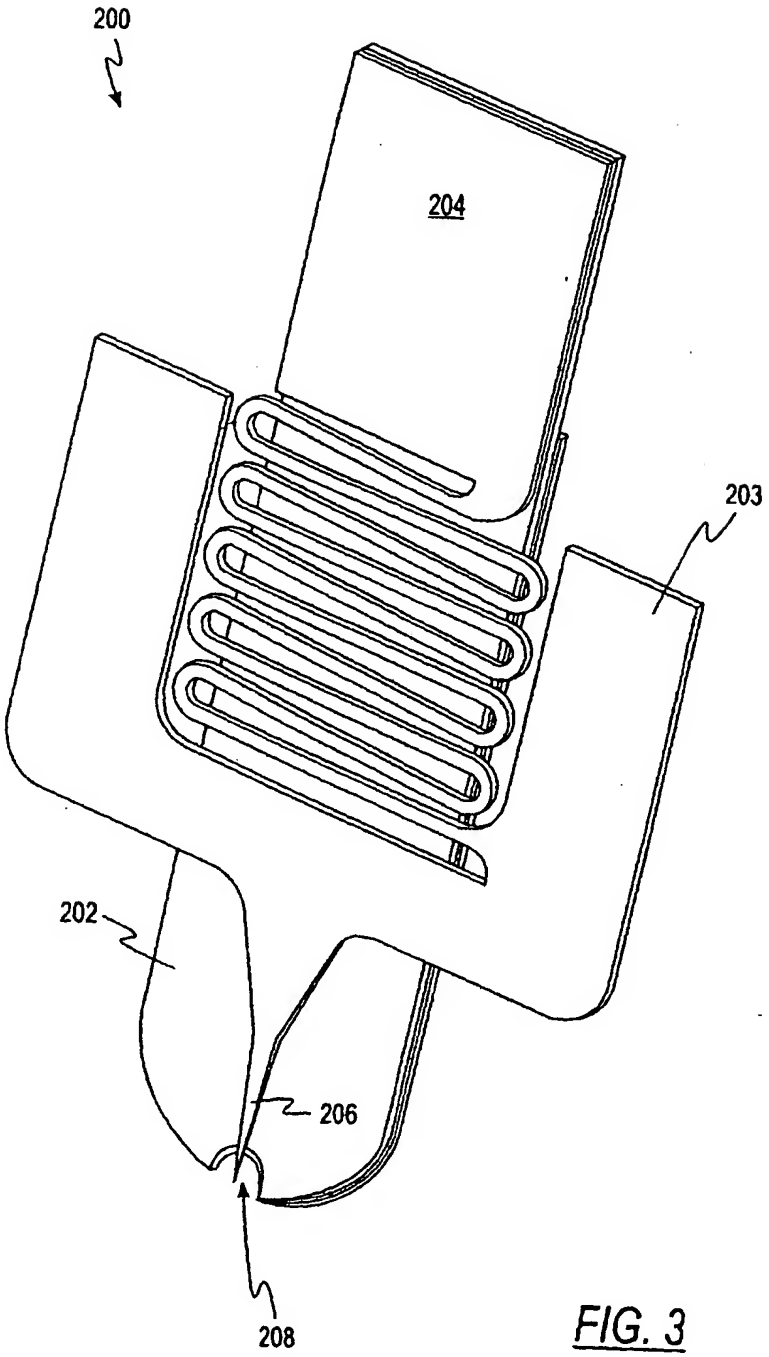

FIG. 3

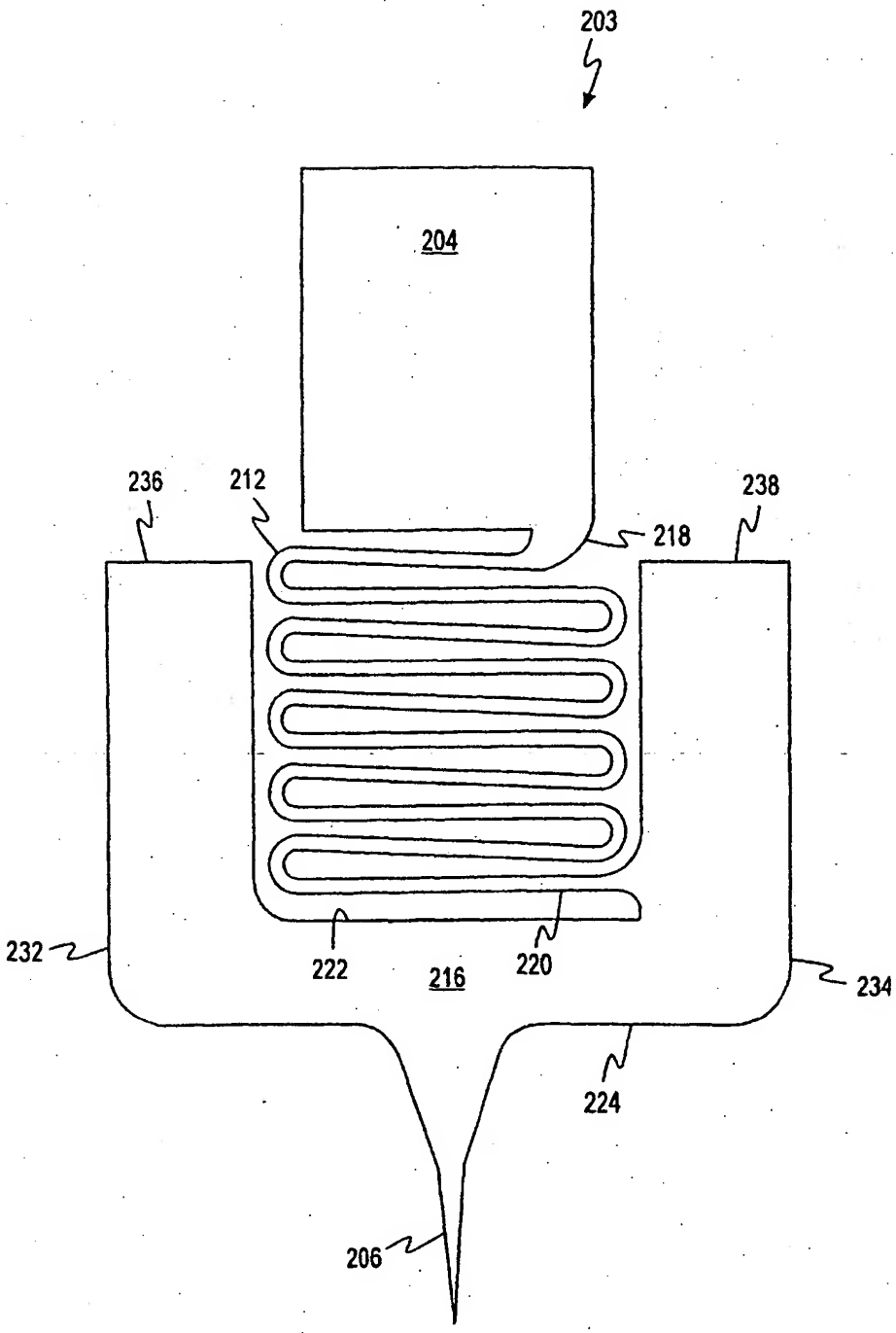

FIG. 4

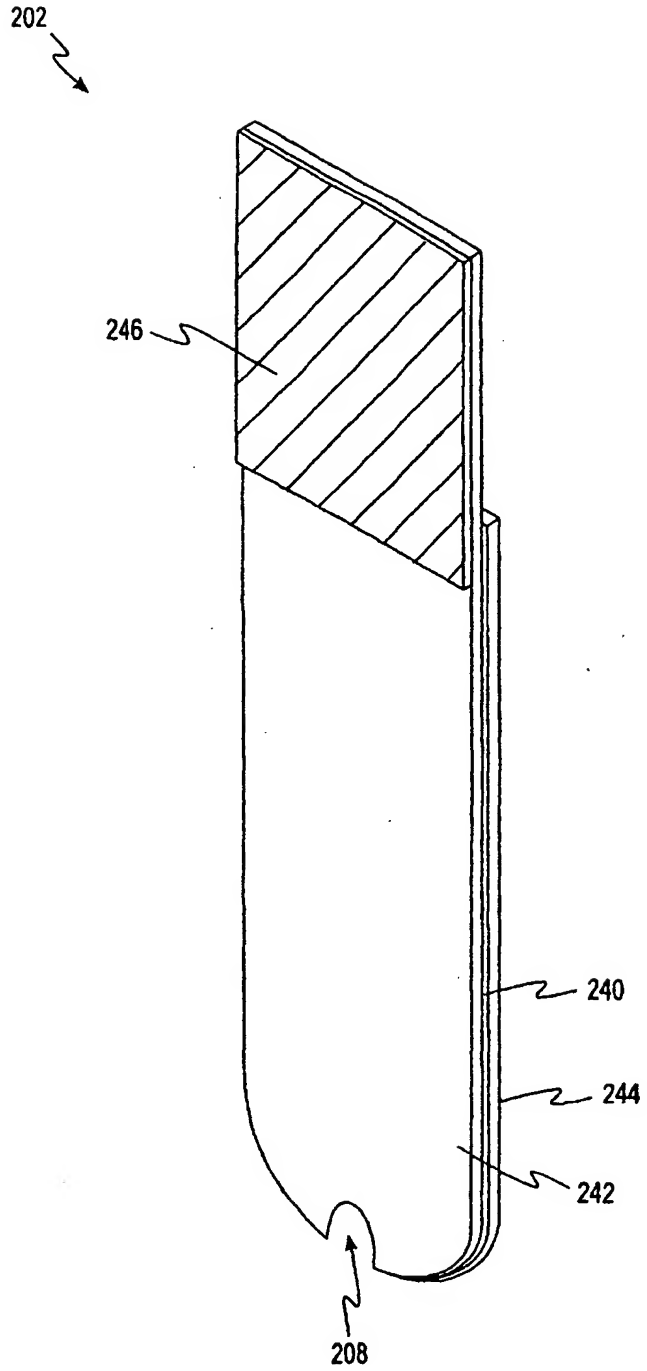

FIG. 5

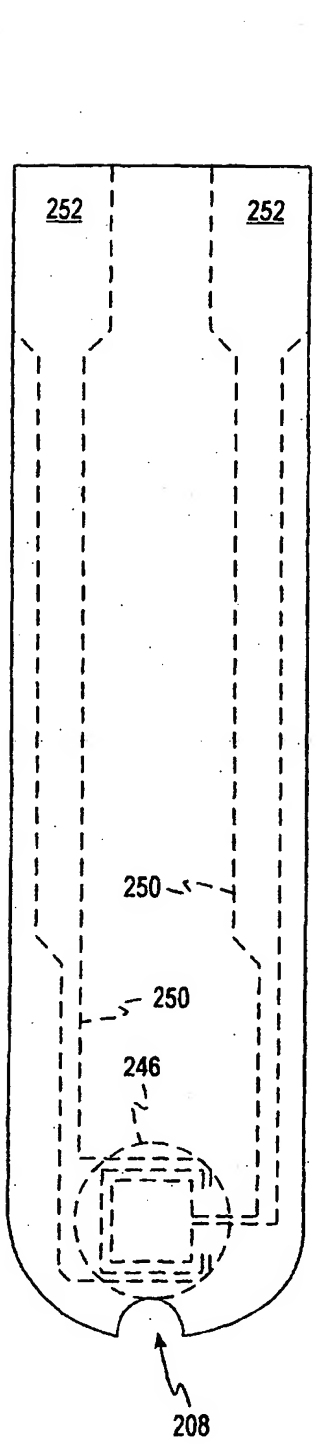

FIG. 6

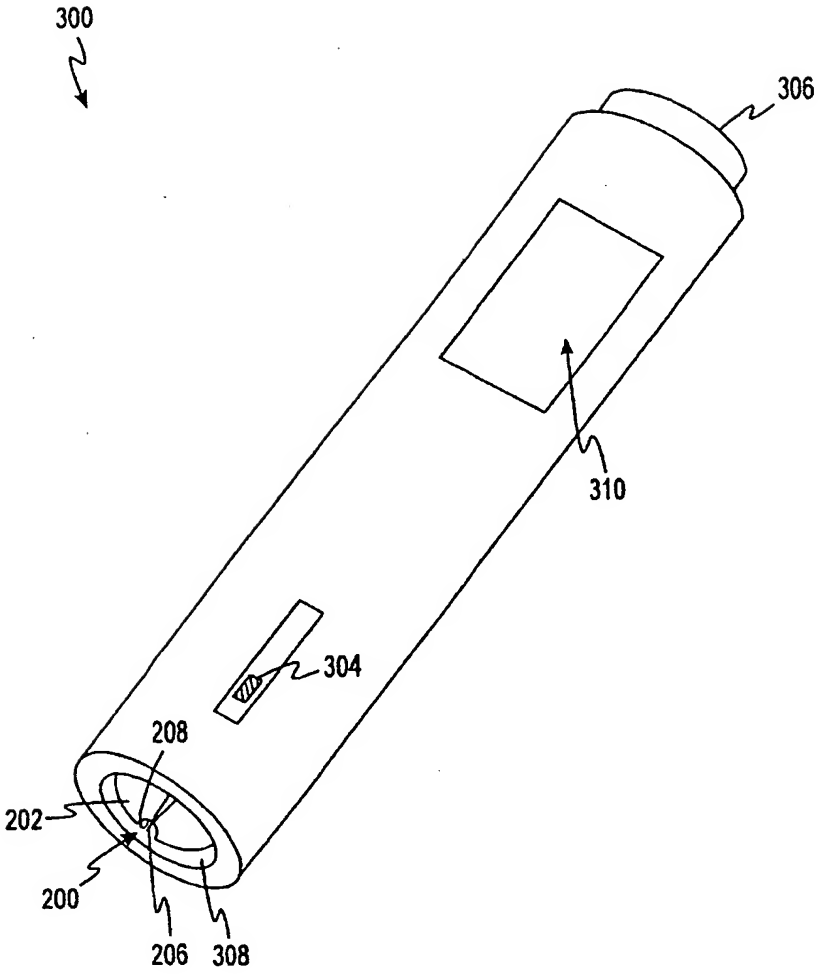

FIG. 7

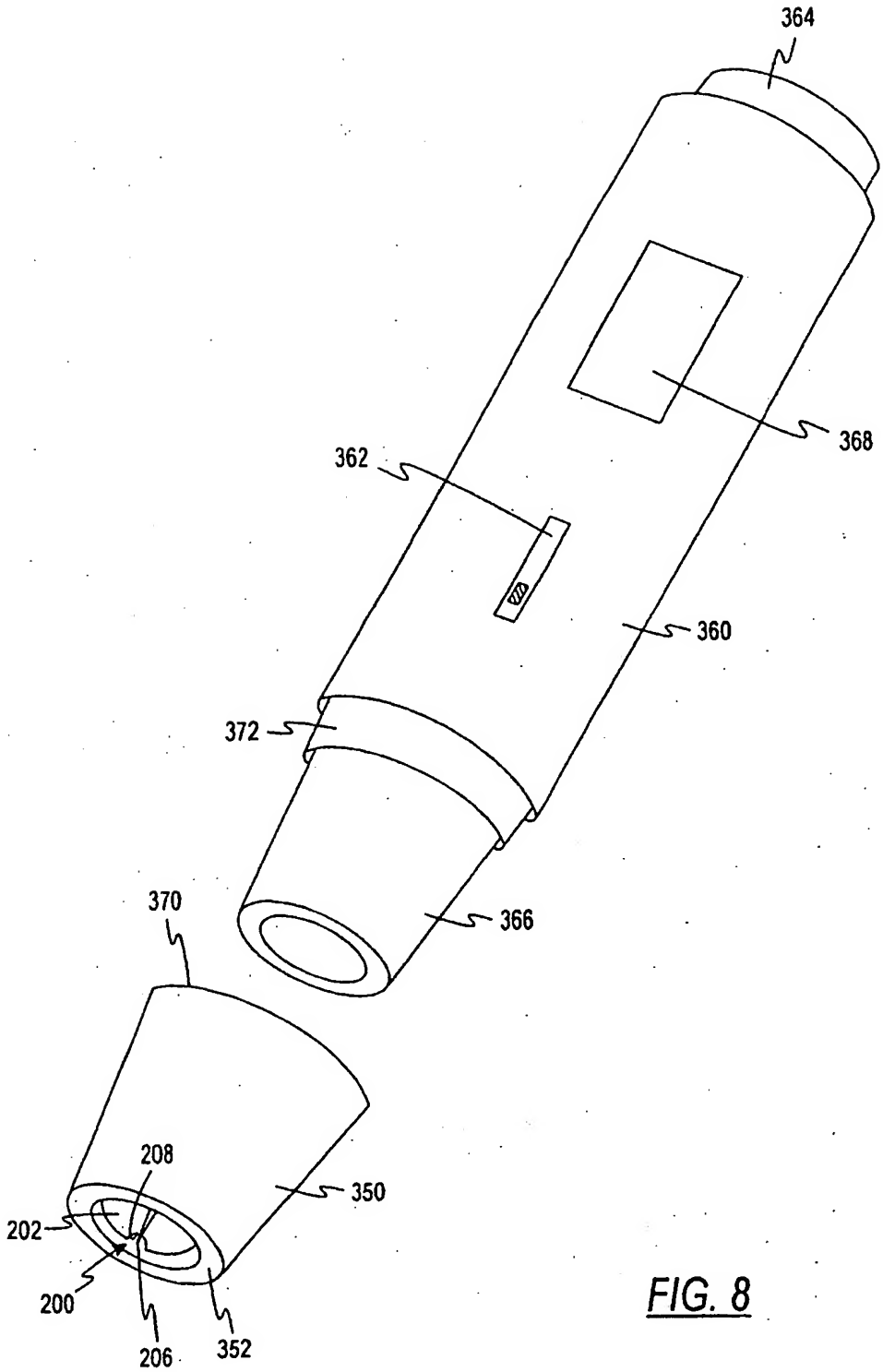

FIG. 8

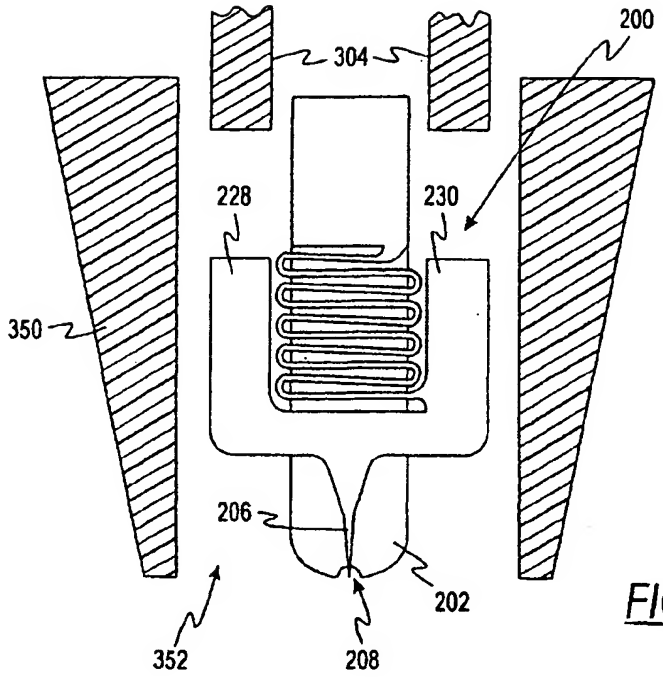
200
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FIG. 9a

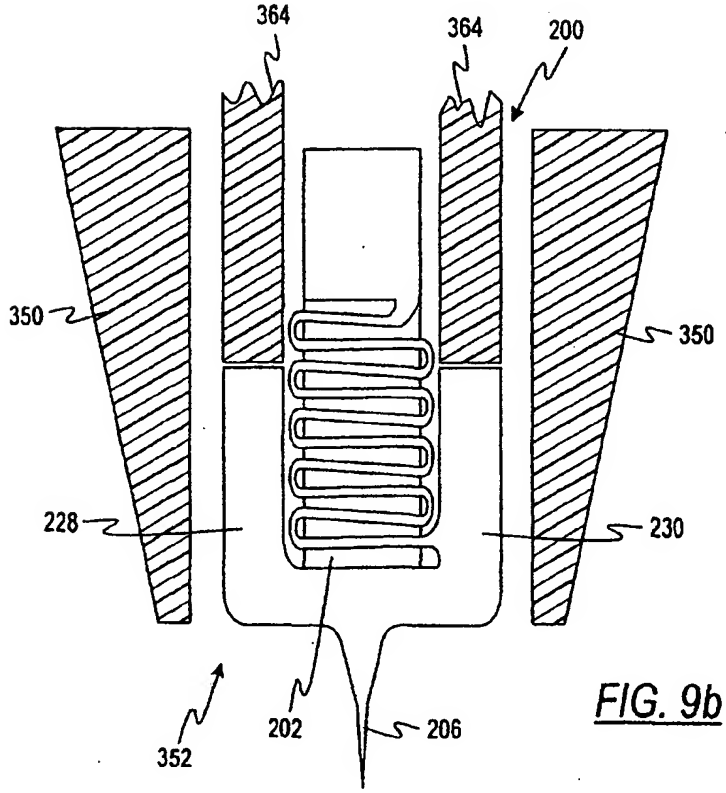
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FIG. 9b